

**Biomedical Study Closure Form**

**\*Note, if your study is on-going please fill out the study renewal form rather than this form.**

**Please type in your responses, print, and then send the original signed copy to our office or email to** **research.ethics@uregina.ca**

**Double click on boxes to check.**

|  |
| --- |
| **1. Title:**  |
| **2. Bio #:**  | **3: Protocol #:** |
| **4. Contact Information:** |
|  | **Name:** | **Department:** | **Phone Number, Email, Fax Number** **(Provide only if different from previously submitted information):** |
| **Principal Investigator:** |  |  |  |
| **Contact Person:** |  |  |  |
| **5. Sponsor/Funding Agency:** |
| **6. What was the target enrollment for the study? \_\_\_\_** |
| **7. How many research participants were screened for the study? \_\_\_\_** |
| **8. How many research participants were enrolled in the study? \_\_\_\_** |
| **9. How many research participants have completed the study? \_\_\_\_** |
| **10. How many research participants have been withdrawn from or discontinued the study? \_\_\_\_\_\_\_\_** **Please provide a reason for each withdrawal (if known):****[ ]  Need for Other Treatment, number \_\_\_\_\_** **[ ]  Withdrawn Consent/Dropped Out, number: \_\_\_\_\_\_** **[ ]  Serious Adverse Event, number: ­­\_\_\_\_\_\_** **[ ]  Other, number \_\_\_\_\_ (Specify reason, if known)** |
| **11. Have any ethical concerns arisen in the course of the study that have not been reported to the Bio REB?** **[ ]  Yes** **[ ]  No** **If Yes, please describe concerns in detail.** |
| **12. Have all serious adverse events been reported to the Bio REB?** **[ ]  Yes** **[ ]  No** **Please attach a Serious Adverse Event Report form for any unreported serious adverse events.** |
| **13. Have all major protocol deviations been reported to the Bio REB? [ ]  Yes [ ]  No** **Please attach a Protocol Deviation Report form for any unreported major protocol deviations.** |
| **14. Please explain why the study is being closed if other than study completed.****[ ]  Data collection completed** **[ ]  Discontinued due to insufficient enrollment** **[ ]  Cancelled prior to initiation****[ ]  Terminated by sponsor** **[ ]  Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_** |
| **15. Provide a brief summary of study results.** |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Principal Investigator and/or Supervisor Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Signature of Student Investigator Date***